



JUNE 23, 2010

HEALTH ADVISORY

FDA Announces Termination Date for 2009 H1N1 Emergency Use Authorizations

During the 2009 H1N1 influenza public health emergency, the Food and Drug Administration (FDA) issued emergency use authorizations (EUAs) that authorized certain unapproved uses of antiviral drugs (Tamiflu, Relenza, Peramivir), N95 respirators and diagnostics kits.

On June 21, 2010, FDA notified the Centers for Disease Control and Prevention that these EUAs will terminate when the public health emergency determination for 2009 H1N1 influenza expires on June 23, 2010. Therefore, after June 23, 2010, the EUAs authorizing the unapproved uses of these products will no longer be in effect.

The following EUAs issued by FDA this past influenza season in response to the 2009 H1N1 influenza pandemic have expired.

1. An EUA that expanded the use of oseltamavir and zanamavir beyond the scope outlined in the package insert mostly pertaining to use of these products in younger children and infants.
2. An EUA that allowed providers to treat influenza patients with IV peramivir.
3. An EUA that allowed the use of certain N95 respirators which are not NIOSH certified and not FDA cleared as medical devices for biological airborne protection (specifically 3M 8210 (M and L), 3M 8000 (M and L), 3M 9210 (M and L), Moldex 2200 (M and L), Moldex 2212 (M and L) and Moldex 2201 (S)).
4. An EUA that permitted the use of in vitro diagnostics using rRT-PCR methods.

For additional information regarding EUA termination, please go to <http://www.cdc.gov/h1n1flu/eua/>. The website includes additional details on what to do with any remaining stocks of these products in state, local or facility inventories.

Categories of Health Alert messages:

- *Health Alert conveys the highest level of importance; warrants immediate action or attention.*
- *Health Advisory provides important information for a specific incident or situation; may not require immediate action.*
- *Health Update provides updated information regarding an incident or situation; no immediate action necessary.*
- *Health Information provides general information that is not necessarily considered to be of an emergent nature.*

This message is being sent to local public health units, clinics, hospitals, physicians, tribal health, North Dakota Nurses Association, North Dakota Long Term Care Association, North Dakota Healthcare Association, North Dakota Medical Association, and hospital public information officers.